

AMENDMENTS TO THE SPECIFICATION

Page 7, fifth paragraph:

B Fig. 8 is another side view of the suture anchor of Fig. 7 rotated 90-~~degree~~- degrees about its central axis;

Page 10, last paragraph, continuing onto page 11:

B2 Although the suture anchor of the present invention may be of any desirable elongated shape, such as a cylinder, the suture anchor of the present invention preferably has at least one generally conical surface. The term "conical surface" is to be understood in its usual sense as all or a portion of the surface generated by a moving line intersecting a fixed curve referred to as the directrix and a fixed point referred to as the vertex or apex. Thus, the suture anchor of the present invention may be a cone (Fig. 1), a truncated cone (Figs. 2-4) such as a frustum (Fig. 2), a cone and cylinder combination (Figs. 5 and 6), or a two cone combination (Figs. 7 and 8). The "central axis" is the line between the apex of the cone and the center of the fixed curve that forms the directrix of the cone. In a right cone, the directrix makes a 90-~~degree~~-angle with the plane of the directrix. One of the simplest embodiments of the invention would be a cone in which the base of the suture anchor and the directrix were the same. In the preferred embodiment shown in Fig. 1, the base of the suture anchor is cut oblique to the directrix.

[Page 12, third paragraph:

B3 The apex angle is commonly determined first. The apex angle of suture anchors 20 and 22 is preferably approximately ~~20-degree.~~ degrees. Thus, for suture anchors 20 and 22, central axis 25 forms an approximately ~~10-degree.~~ angle with the conical surface 40. This is shown for suture anchors 20 and 22 in Figs. 1 and 2, respectively. The apex angle A of suture anchors 322, 522 and 722 is preferably approximately ~~15-degree.~~ degrees. Thus, for suture anchors 322, 522 and 722, central axis 25 preferably forms an approximately ~~7.5-degree.~~ angle with conical surfaces 340, 540 and 740, respectively. This is shown for suture anchors 322, 522 and 722 in Figs. 3, 5 and 7, respectively.

[Page 14, second paragraph:

B4 Apex 24, or a portion thereof, is useful for cutting through cancellous bone tissue once suture anchor 20 passes through the cortical bone tissue. Angle A of apex 24 is selected to efficiently cut through cancellous bone tissue and can range from ~~10-degree.-60-degree.~~ 10 degrees-60 degrees. Preferably, apex angle A is between ~~10-degree.-20-degree.~~ 10 degrees-20 degrees. The exact angle will depend on the apparatus used, and most typically is approximately ~~15-degree.-20-degree~~ 15 degrees-20 degrees.

[Page 14, last paragraph, continuing onto page 15:

B5 For greater strength in the apical area, it may be desirable to cut off the apex of the conical suture anchor

to form a flattened trailing end 26 (Fig. 2), 326 (Fig. 3), 526 (Fig. 5), 726 (Fig. 7). The angle at which the apex is cut may result in a frustoconical suture anchor 22 (Fig. 2), or a truncated conical suture anchor 322 (Figs. 3 and 4), 522 (Figs. 5 and 6), 722 (Figs. 7 and 8). The amount by which the cone's apex is truncated should preferably maximize the structural strength of the apical region of the suture anchor, while retaining a general conical shape. This enables travel through cancellous bone tissue during reorientation and positioning of the suture anchor after insertion. Preferably, the apex is cut so that the trailing end formed is at an approximately 45-degree angle T with the conical surface to form a truncated conical suture anchor 322, 522, 722 as shown in Figs. 3, 5, and 7.

[Page 15, last paragraph, continuing onto page 16:

The specific angle at which base 28 is cut with respect to the central axis is determined primarily by the size of the patient bone hole, to achieve the most easily insertable suture anchor. The measurement of the angle formed by the central axis and the conical surface and the desired length of the suture anchor also affect the angle at which base 28 should be cut. The suture anchor must be sufficiently narrow, in at least one orientation, such that it is able to fit through the patient bone hole in which the suture anchor is to be positioned. Thus, when the suture anchor is inserted into the patient bone hole (with base 28 parallel to the walls of the patient bone hole) trailing edge 32 should be able to fit into the patient bone hole as well in order to ensure that the remainder of the suture anchor will be able to fit through the patient

34 bone hole. Preferably, the widest part of the suture anchor is approximately 0.2-0.5 mm less than the patient bone hole. Preferably, base 28 is cut at an angle of approximately ~~45-degree.~~ degrees with respect to the central axis. Typically, the resulting angle C at the trailing edge is between ~~90-degree.~~ degrees-~~165-degree.~~ degrees, and most preferably approximately ~~128-degree.~~ degrees.

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[Page 18, last paragraph, continuing onto page 19:

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37 Suture anchor 522 is formed with a conical surface 540 up to bores 34 and 36 and a cylindrical surface 542 extending from bores 34 and 36 to base 28. Such a suture anchor may be generally described as having a first conical surface 540, a base 28 closing off the open end of the conical surface, a central axis 25, and an anchor bore 34 across said conical surface with a cylindrical surface 542 extending between the open end of the conical surface and the base. The diameter of cylindrical surface 542 is preferably substantially equal to the diameter of conical surface 540 at transition point 544 from conical to cylindrical. Thus, provided that the suture anchors are of comparable length and apex angle, the widest part of suture anchor 522 is narrower than the widest part of suture anchors 20, 22, and 322 and, accordingly, suture anchor 522 can fit in a narrower patient bone hole. Because of its strength and size, suture anchor 522 is a particularly preferred embodiment. When measured from end to end, at its largest distance, suture anchor 522 is preferably approximately 0.44 in. (1.1176 cm) in length.

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[Page 22, last paragraph, continuing onto page 23:

38 Insertion tool ~~40~~ 41 of Fig. 9 has a substantially straight elongated body 42 ending with insertion end 44, which is inserted inside anchor bore 34 of the suture anchor. Bead 46 demarcates insertion end 44 from the remainder of body 42 and prevents body 42 from entering anchor bore 34. The diameter of insertion end 44 should be sufficiently wide to provide a secure fit inside anchor bore 34 of the suture anchor (also accounting for the amount of suture material, if any, inside anchor bore 34). The diameter of bead 46 should be substantially larger in diameter than anchor bore 34 in order to limit movement of insertion end 44 through anchor bore 34.

[Page 23, second paragraph:

39 Insertion tool 48 of Fig. 10 also has a substantially straight elongated body 50 ending at insertion end 52. Like insertion tool ~~40~~ 41, insertion end 52 of insertion tool 48 is distinctly demarcated from the remainder of body 50 to thereby limit movement of body 50 through anchor bore 34. In this instance, insertion end 52 is narrower than body 50 and distinctly begins at step 54. Insertion end 52 must be sufficiently thick to form a secure fit within anchor bore 34 of the suture anchor during insertion into the patient bone hole (also accounting for the amount of suture material, if any, inside anchor bore 34). It will be appreciated that one or both sides of insertion tool 48 may be stepped.

[Page 24, second paragraph:

B<sup>10</sup> Insertion tools ~~40~~ 41, 48, 56, and 56' may have a handle (not shown) at the end opposite insertion end 44, 52, 60 to facilitate gripping of the insertion tool during insertion of the suture anchor into the patient bone hole. Typically, the hand grip would be wider and longer than body 42, 50, and 58.

[Page 24, last paragraph, continuing onto page 25:

B<sup>11</sup> For reasons as will be described in connection with the method of insertion, at least insertion ends 44, 52, and 60 of insertion tools ~~40~~ 41, 48, 56 and 56', respectively, should be formed from a material having elastic properties, preferably superelastic properties, such as a shape memory material. The elastic or superelastic properties of the material should be such that the insertion end is not substantially permanently deformed during insertion of the suture anchor and will substantially return the insertion end to an initial configuration (generally the configuration of the insertion end at the time it is initially mounted in anchor bore 34, prior to insertion of the suture anchor into the patient bone). The preferred material for at least the insertion end of the insertion tool is a nickel titanium alloy. Such materials are available commercially, under the names NITINOL.TM. or TINEL.TM. (RayChem) or SENTINOL.TM. (GAC International, Inc.). Such shape memory alloys having superelastic properties are well known in the art. See, e.g., U.S. Pat. Nos. 4,505,767, and 4,565,589. However, any other shape retaining material sufficient for properly

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inserting the suture anchor of the present invention into a patient bone hole may be used. See e.g., Shirai and Hayashi, Mitsubishi Technical Bulletin, 184, pp. 1-6 (1988).

[Page 26, first paragraph:

B<sup>12</sup>  
In Fig. 13, one end of suture 64 is threaded through anchor bore 34 and looped around the conical surface of suture anchor 20 adjacent leading edge 30. Thus, suture 64 passes through suture anchor 20 only once, as thread through the eye of a needle. When threaded in this manner, suture 64 can freely travel through anchor bore 34. When threaded in this manner, pulling one of the free ends of suture 64 may cause the suture anchor to rotate approximately 90-degree degrees.

[Page 27, last paragraph, continuing onto page 28:

B<sup>13</sup>  
As shown in Fig. 16, suture 64 is threaded through anchor bore 34, and suture anchor 20 is mounted on insertion end 44 of insertion tool ~~40~~ 41. Insertion end 44 enters anchor bore 34 adjacent trailing edge 32 of suture anchor 20 and exits (if at all) adjacent leading edge 30. Because insertion end 44 of tool ~~40~~ 41 is securely positioned within anchor bore 34, anchor bore 34 is not easily distinguishable, in the Figs., from the outer surface of insertion end 44. Anchor bore 34 is preferably drilled parallel to base 28 such that force applied by the insertion tool advances the leading edge of the suture anchor toward the patient bone hole. Insertion tool ~~40~~ 41 is positioned parallel to the longitudinal axis of patient

B<sup>13</sup>  
bone hole 70, maintaining anchor bore 34 and base 28 (if anchor bore 34 is drilled parallel to base 28) parallel to patient bone hole 70, as well. Leading edge 30 of suture anchor 20 is positioned to be the first portion of suture anchor 20 to enter patient bone hole 70.

[Page 28, last paragraph:

B<sup>14</sup>  
Once the conical surface extending between leading edge 30 and apex 24 encounters patient bone hole 70, suture anchor 20 begins to rotate or reorient, as shown in Fig. 18, in order to fit into patient bone hole 70. Main body 42 of insertion tool ~~40~~ 41 is maintained parallel to patient bone hole 70. Thus, when suture anchor 20 reorients, insertion end 44 bends.

[Page 29, first paragraph:

B<sup>15</sup>  
Typically, insertion end 44 is bent to the greatest extent immediately before trailing edge 32 leaves the portion of patient bone hole 70 in patient cortical bone tissue 74, as shown in Fig. 19. Once trailing edge 32 begins traveling through patient cancellous bone tissue 76, insertion end 44 begins to resume its initially straight configuration, as shown in Figs. 20 and 21, thereby deploying the suture anchor. Preferably main body 42 of insertion tool ~~40~~ 41 is not as flexible as insertion end 44, and remains straight throughout the insertion procedure.

[Page 29, last paragraph, continuing onto page 30:



314 Once apex 24 has cleared patient cortical bone tissue 74, and the entire suture anchor is in cancellous bone tissue 76, insertion end 44 of insertion tool 40 41 is able to return to its original configuration, as shown in Fig. 22. The pointed shape of apex 24 allows suture anchor 20 to more easily cut through cancellous bone tissue 76 so that the suture anchor may be reoriented and secured in its final position. As shown in Fig. 23, insertion tool 40 41 can then be disengaged from the suture anchor and removed. Pulling the suture ~~anchor~~ 64 up and away from patient bone 72 at this point may aid in dismounting the suture anchor from the insertion tool in addition to rotating and thereby properly seating suture anchor 20 in cancellous bone tissue 76. Preferably suture 64 is once again pulled up and away from patient bone 72 after the insertion tool is removed to firmly position ~~35~~ suture anchor 20 in patient bone 72, preferably against the undersurface of cortical bone 74, within the transition region between cortical bone matter 74 and cancellous bone matter 76. Typically, suture 64 will be substantially centered within patient bone hole 70, and suture anchor 20 will be substantially horizontal. Suturing of body tissue to patient bone 72 can now be commenced.

Page 31, third paragraph:

317 The threaded suture anchor was mounted on the insertion tip of the insertion tool and advanced into the bone hole with the body of the insertion tool parallel to the longitudinal axis of the bone hole. Once the suture anchor was deployed, the insertion device was removed and the ~~end~~ ends of the stainless steel suture were tied to form a loop. The suture anchors were tested to anchor

failure using a spring loaded scale with an automatic  
marker. Failure strength greater than 30 lbs. exceeds  
industry standards.

Page 34, third paragraph:

Furthermore, if desired, suture anchor 822 can also  
have a tapered opening 36A for receiving the tapered distal  
end of insertion tool ~~40A~~ 41A.